Regulation, Reimbursement and Health Technology Assessment

Why you need to think about these even during R&D

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Overview

• Introduction
• Regulation
• Reimbursement
• Technology Assessment
Definitions

• Regulation
  – Process that governs product safety & efficacy

• Reimbursement
  – Process to receive insurance payment

• Health Technology Assessment
  – Process to sell into public health system
The Regulatory Environment
Regulatory Environment

• Why Regulation
  – Safety of products from public perspective
  – Product claims are valid and based on evidence
  – Add value to treatment options (US FDA)
Who Regulates

- Most nations of the world
  - FDA (USA)
  - TGA (Australia)
  - CE (Europe)
  - CFDA (China)
  - PMDA (Japan)
Regulatory Environment

• What is Regulated?
  – Drugs
  – Vaccines
  – Medical devices
  – *In vitro* diagnostics
  – Complementary medicines*
# Medical Device Classification (TGA)

<table>
<thead>
<tr>
<th>Medical Device Classifications</th>
<th>Examples</th>
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<tbody>
<tr>
<td>Class I</td>
<td>Elastic bandages, tongue depressors, cervical collars, slings, non-sterile dressings</td>
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<tr>
<td>Class IIa</td>
<td>X-ray films, intravenous tubing, contact lenses, catheters</td>
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<tr>
<td>Class IIb</td>
<td>Blood bags, dressings for severe wounds, condoms</td>
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<tr>
<td>Class III</td>
<td>Coronary artery probes, intrauterine contraceptive devices, medical devices that contain medicines, such as dressings with an anti-microbial agent</td>
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<tr>
<td>Active implantable medical devices</td>
<td>Pace makers, cochlear implants</td>
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Medical Device Regulation (TGA)

• Pre-market
  – Design History File
  – Manufacturer conformity assessment
  – TGA evaluates available evidence for high risk devices
  – TGA approves device being included on the ARTG

• Post-market regulation consists of:
  – Manufacturer maintains current conformity assessment
  – Manufacturer monitors ongoing performance and safety
  – TGA notified of any serious issues
  – TGA conducts random and targeted assessments of medical devices

The regulators will go back to the start of the development process to verify the intended use and how changes in design were controlled to ensure the device is fit for purpose.
Drug Regulation (FDA)
Drug Regulation (FDA)

• Center for Drug Evaluation and Research (CDER)
  – Evaluates new drugs for approval in US
    • Harm minimisation
    • Effectiveness
    • Value to health system
Drug Regulation (FDA)

1. New chemical entity
2. Animal testing (various species)
3. Investigational New Drug (IND) application and review
   a) Drug composition
   b) Initial testing
   c) Manufacture process
   d) Testing protocol
Drug Sponsors Clinical Trials

4. Phase I clinical trial
   a) 20-80 subjects
   b) Safety focus

5. Phase II clinical trial
   a) 100+ subjects
   b) Effectiveness

6. Phase III clinical trial
   a) 1000+ subject
   b) Safety and efficacy
New Drug Application (FDA)

1. Review meeting (prior to submission)
2. New drug application
3. Review process
4. Drug labelling
5. Facility inspection
6. Drug approval/response letter
Post Market Monitoring (FDA)

- Periodic safety updates
- MedWatch
  - Consumer/physician adverse event reporting
Regulation Need to Know

• Regulatory affairs is a specialist area
• Get regulatory advice early
• Correct record keeping critical even at R&D phase
• Errors or oversights can cause costly delays
  – QRxPharma
  – Tissue Therapies
Reimbursement
Reimbursement

• Regulatory approval allows you to sell a product
• To be paid, a product is either sold full price without reimbursement to the patient; or
• Is accessed by private and public insurance organisations, who determine the level of reimbursement they will pay
Example

Impedimed - announced the Centers for Medicare and Medicaid Services (CMS) has published the valuation for CPT® Category I Code 93702 for the Company’s L-Dex procedure for the assessment of lymphoedema at US$112.67 when billed by a hospital outpatient facility.
Health Technology Assessment (HTA)
Health Technology Assessment

• An evidence-based process leading to addition of a new health technology to an approved provider listing in the public health system.

Health Technology Assessment (UK)

• Health Technology Assessment
  – Funds independent research about the effectiveness, costs and broader impact of healthcare treatments.
Health Technology Assessment (UK)

• National Institute for Health and Care Excellence (NICE)
  – Assess the clinical and cost effectiveness of health technologies:
    • Pharmaceuticals
    • Biopharmaceuticals
    • Procedures
    • Devices
    • Diagnostic agents
Conclusion

• R&D is the first step in progressing a new health technology to market
• Prior to being released for public use, a new health technology has to be shown to be safe, effective and deliver value
• Payers need to be convinced of this value